DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: **June 29, 2012**

TO: **All Part D Sponsors and Interested Stakeholders**

FROM: **Cynthia G. Tudor, Ph.D., Director**
Medicare Drug Benefit and C&D Data Group

SUBJECT: **DRAFT Additional Guidance Related to Improving Drug Utilization Review Controls in Part D—Request for Comments**

This memorandum responds to comments received on the Contract Year 2013 Call Letter ("2013 Call Letter") and provides draft additional guidance regarding the section entitled, "Improving Drug Utilization Review Controls in Part D," of the 2013 Call Letter, which sets forth how Part D sponsors can comply with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of prescribed covered Part D drugs. Specifically, this memorandum goes into more detail about the components of DUR Programming and Clinical Case Management and provides sample letters for notifications to prescribers and the beneficiary as part of clinical case management. It also describes CMS's planned approach to monitoring Part D sponsors' implementation of the DUR controls and case management in 2013. Finally, this memorandum addresses data sharing between sponsors when a Part D enrollee under an overutilization protocol disenrolls from one plan and re-enrolls in another, including the records and actions that should be shared, as well as how to coordinate transfers of information and facilitate manual processes to do so.

On two separate occasions, CMS has solicited comments on this process. To finalize this guidance, we would like to solicit comments on the sample letters that are included. Please submit such comments to PartDPolicy@cms.hhs.gov using the Subject Line "Comments on Improving Drug Utilization Review Controls in Part D" no later than **Friday, July 20, 2012.**

Components of Level Three: Improved Retrospective DUR Programming and Clinical Case Management

We previously set forth our expectation regarding components of an opioid overutilization review program in the 2013 Call Letter. From comments we received, we understand some sponsors would find it useful if we provided more specificity as to implementation of such a program. Therefore, we describe a sample program below and provide additional detail to illustrate our view of how such a program could be implemented. This is not intended as a required step-by-step process that Part D sponsors must follow, but rather, a more detailed description of our conception of a reasonable, effective

approach to complying with the DUM requirements of 42 C.F.R §423.153 et seq. in order to assist those Part D sponsors who have requested such specificity.

One approach that could comply with 42 CFR§ 423.153 et seq. would include the following specific features:

A. Documentation of the program in written policies and procedures that are periodically reviewed, updated as necessary, and approved by the plan's P&T committee;

B. Methodology to identify potential opioid overutilizers based on drug claims data through clinical thresholds and prescription patterns set by the P&T committee that would trigger case management and include the following elements:

1. The P&T committee documents the bases for the clinical thresholds and prescription patterns;

(As part of establishing the bases for clinical thresholds, we note that P&T committee members may be interested in reviewing pain management rules for chronic noncancer pain that are used in the state of Washington when a patient's cumulative daily morphine equivalent dose (MED) is, currently, greater than or equal to 120 mg. See

http://www.doh.wa.gov/PublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/PainManagement.aspx

Additional information about the risks of overdose during long-term opioid therapy may be found in a study published in the *Annals of Internal Medicine*, 2010; 152:85-92.

Based on CMS analysis, after excluding cancer and hospice patients, we estimate that approximately 225,000 Medicare Part D beneficiaries received more than 120 mg MED daily for at least 90 consecutive days in 2011. This is roughly 0.7% of the total Part D population in that year. We continue to investigate other factors associated with high utilization of opioids, such as diagnoses, number of prescribers and number of pharmacies, and will provide further data in the final version of this guidance.)

2. The policies and procedures address the required contents of the case management files of potential opioid overutilizers, including what clinical content must be included in a case file (See also "*Meaning of Records and Actions*" below for documents that we would expect to be included in the case management file);

C. Protocol to exclude as early as possible from the retrospective DUR and case management process those beneficiaries who have legitimate diagnoses that may warrant high opioid use (e.g., cancer patients or others who need palliative care), or who are borderline cases in light of the clinical thresholds and prescription patterns set by the P&T committee;

D. Communication with prescribers and beneficiaries about case management actions (See also *Notification to Prescriber(s), the Beneficiary and Sample Letters* below);

1. Written inquiries to the prescribers of the opioid medications about the appropriateness and medical necessity of the apparent high dosage;

2. Notification to beneficiaries that their high opioid medication utilization is being reviewed as a health care safety issue;

3. At least three (3) attempts to schedule telephone conversations with all prescribers and, separately, the beneficiary, to determine the appropriate level of opioid use are made within a reasonable period (e.g., a ten (10) business day period) from the issuance of the notification. The telephone conversations should comply with the following:

a. the personnel communicating with prescribers have appropriate credentials, as established by the P&T committee;

b. the clinician-to-clinician communication includes information about the existence of multiple prescribers and the beneficiary's total opioid utilization, and the plan's clinician elicits information about any complicating factors in the beneficiary's treatment;

c. the policies and procedures set forth the documentation required to memorialize the telephone conversations with prescribers and the beneficiary;

3. After discussion or communication about the appropriate level of opioid use, the consensus reached by the prescribers is implemented by the sponsor, with a beneficiary-level claim edit, as appropriate;

4. Written notice is issued to the beneficiary and the prescriber(s) informing them of the results of case management;

a. If the result will be a decreased availability of opioids for the beneficiary, notice is issued to the beneficiary at least fifteen (15) business days in advance of this action, which includes information about claim edits to be imposed and appeal rights, and the notice is copied to the CMS account manager and the following central office mailbox PartDPolicy@cms.hhs.gov with the subject line "Notice of Beneficiary Claim Edit";

b. If the result is that the current level of opioids is determined to be medically necessary for the beneficiary, the beneficiary and prescribers would be promptly so notified.

5. In cases of non-responsive prescribers, the sponsor implements a beneficiary-level claim edit to prevent coverage of an unsafe level of drugs;

E. If the affected beneficiary disenrolls from the plan voluntarily, there is a method for the existing sponsor to transfer information (including the case management file) to the new sponsor in accordance with applicable law (See also *Data Sharing Between Sponsors* below);

F. The sponsor's Part D Medication Therapy Management (MTM) Program may identify overutilization of opioids as a criterion for targeted reviews and interventions;

G. There are policies and procedures for referrals to the appropriate agencies in accordance with the policy set forth in Chapter 9 of the Medicare Prescription Drug Benefits Manual, if the sponsor believes a beneficiary, prescriber, and/or pharmacy is involved in fraudulent activity.

While we have described here more specific features of an "Improved Retrospective DUR Programming and Case Management" approach, we intend the features described in the 2013 Call Letter to be sufficiently flexible to accommodate different sponsor approaches to addressing overutilization. Regardless of whether a sponsor adopts features consistent with the 2013 Call Letter or the more specific parameters set forth here, the sponsor will be expected to follow the overutilization review program it establishes. If the plan denies coverage of medically necessary opioids based on a determination of overutilization made in contravention of its overutilization program, or conversely, covers medically unnecessary opioids in contravention of its program, absent documented justification, CMS may consider the plan to be out of compliance with the requirements at 42 C.F.R. § 423.153 et seq.

Sample Letters for Notification to Prescribers and the Beneficiary as part of Clinical Case Management

In order to assist sponsors in complying with the standards we described in the 2013 Call Letter, we stated that we would provide sample letters. Included with this guidance are the following draft sample letters:

1. Written inquiry to a prescriber of the opioid medications about the appropriateness, medical necessity, and safety of the apparent high dosage (See Sample Part D Drug Overutilization Initial Prescriber Inquiry Letter CY2013);
2. Initial notice to the beneficiary that the beneficiary's high opioid use is being reviewed as a health care safety issue (See Sample Part D Drug Overutilization Initial Beneficiary Inquiry Letter CY2013);
3. A notice that would be issued to the beneficiary and the prescribers informing them that the result of case management is that the opioid use was determined to be appropriate and medically necessary, and is therefore covered (See Sample Part D Drug Overutilization Beneficiary and Prescriber No Change Confirmation Letter CY2013);
4. A notice that would be issued to the beneficiary and the prescribers informing them that the results of case management will be a beneficiary-level claim edit that allows coverage of none, or only a certain amount of, pain medication, and that includes information about appeal rights (See Sample Part D Drug Overutilization Notice of Beneficiary Claim Edit Letter CY2013);
5. A cover memorandum that would be used when data is shared between sponsors about an overutilization protocol. (See Sample Part D Drug Overutilization Sponsor Data Transfer Memorandum CY2013; See also *Data Sharing Between Sponsors* below).

CMS Monitoring

As noted in the 2013 Call Letter, we will be closely monitoring sponsor performance and beneficiary impact of the Part D drug overutilization policy, and we are in the process of developing monitoring tools. For instance, we are developing an opioid outlier report, which will be shared with Part D sponsors for feedback, to assist CMS in monitoring sponsors' implementation of the overutilization

policy. This report will identify beneficiaries who are potential opioid overutilizers from their prescription drug event (PDE) records. Sponsors may be asked to respond whether the beneficiaries' opioid use has already been investigated, if there is an acceptable justification for the beneficiaries' opioid use, and if not, if an overutilization protocol has been implemented for the beneficiaries.

We also specifically acknowledged in the 2013 Call Letter that the opioid class of medication presents many challenges for sponsors to ensure beneficiary safety and prevent fraud, waste and abuse. In this regard, we understand that implementation will take some time, and our expectation is that by the end of the first quarter of 2013, sponsors will have begun to engage in case management of the highest priority of identified potential opioid overutilizers in their Part D plans. Thus, an incremental approach in the early stages of implementation of case management would be acceptable.

Data Sharing Between Sponsors

In order to address beneficiaries who are subject to an overutilization protocol who disenroll from a Part D plan and enroll in another and attempt to re-engage in overutilization, we made clear in the 2013 Call Letter that a sponsor can share with a successor sponsor the "records and actions" generated by an overutilization review. We further stated that sponsors should promptly coordinate such transfers of information and facilitate manual processes when necessary to convey their documented case files in the absence of established automated processes.

1. Meaning of Record and Actions

In the 2013 Call Letter, we referred to "record and actions" as "the record from the retrospective DUR review/case management, as well as beneficiary-specific POS edit." This means the case file from the retrospective DUR review/case management upon which the decision to implement an overutilization protocol was based, which could include, but need not be limited to:

a) clinical threshold and/or prescription pattern that triggered case management;
b) copies of medical records;
c) beneficiary drug utilization history;
d) correspondence with prescriber(s) and the beneficiary;
e) notes documenting telephone conversations;
f) documentation of the decision arrived at through case management; and
g) description of the beneficiary-specific POS edit that was implemented.

While the minimum necessary information must be shared in accordance with the privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA), sponsors are also reminded that the file should be comprehensive enough to support the decision to implement the overutilization protocol. However, we note that we would not expect sponsors to share proprietary business information with another sponsor.

2. Coordination and Facilitation of Manual Processes

In order to coordinate transfers of beneficiary information and facilitate such manual processes, sponsors will be expected to provide an "overutilization" contact in HPMS when prompted by CMS, which will be made available to all sponsors. We envision that sponsors should use this contact information to transfer the overutilization "record and action" within 2 weeks of receiving TRR notice of the disenrollment and enrollment in a new plan by a beneficiary for whom the existing sponsor has implemented an overutilization protocol. To meet this deadline, we believe sponsors will need to program their enrollment databases to generate an alert when an enrollee under an overutilization protocol disenrolls, so the existing sponsor can promptly share the records and actions generated by its overutilization review with the successor sponsor identified in the TRR. Transfers of beneficiary-level information must be made securely in accordance with sponsors' responsibilities as Covered Entities under HIPAA, such as via secure e-mail of PDF documents or via common carrier with a tracking feature.

After reviewing the information received, the successor sponsor might concur with the prior sponsor's overutilization protocol and implement it without change, or modify it, if it believes the documentation adequately supports the protocol as is or with modification. However, if the successor sponsor believes the documentation is inadequate for any overutilization protocol, it should conduct its own research on the beneficiary's opioid use and make its own determination. If the successor sponsor implements the same, a modified, or a different overutilization protocol, for the beneficiary, it would inform the affected prescribers and beneficiary in writing as described in the section *Components of DUR Programming and Clinical Case Management* above.

Conclusion

Although we have provided additional detail in this memorandum, we remain open to feedback on implementation of the overutilization policy set forth in the 2013 Call Letter. In particular, as sponsors gain experience implementing retrospective DUR and case management, we may identify and share best practices.

Additionally, we understand that the Part D overutilization policy cannot completely prevent overutilization, as pharmacies may still dispense, and beneficiaries may still purchase, drugs outside of Part D coverage. Nevertheless, CMS expects that sponsors will meet their Part D program obligations by employing more effective concurrent and retrospective DUR programs to address overutilization, in order to protect beneficiaries' health and welfare and to prevent federal tax dollars from being spent on fraud, waste and abuse. We also note that prescribers and pharmacies have ethical and legal responsibilities regarding drug overutilization. For instance, nearly all states have Prescription Monitoring Programs ("PMPs") of which prescribers and pharmacies may make inquiries. PMPs collect, monitor, and analyze prescribing and dispensing data submitted by pharmacies and practitioners. The data are then used to support states' efforts to reduce prescription drug abuse and diversion. Part D

sponsors may consider encouraging prescribers to use PMPs, which may reduce the number of potential overutilization cases requiring case management.

Part D sponsors might also consider encouraging prescribers to prescribe medications more likely to be overutilized or not tolerated and therefore wasted in shorter days supplies, as appropriate. We note that, beginning 2014, Part D sponsors will be required to apply a daily cost-sharing rate to certain prescriptions that are dispensed in quantities that are less than a month's supply. *See* 77 Fed. Reg. 22072, 22126 (April 12, 2012).

Questions about this memorandum or the Part D overutilization policy should be directed to PartDPolicy@cms.hhs.gov using the Subject Line "Overutilization."

Sample Part D Drug Overutilization Initial Prescriber Inquiry Letter CY2013

Instructions: This sample could be used to notify prescribers that the plan's record shows that one of their patients is being prescribed a drug(s) from the opioid class in a potentially unsafe high dosage, which has triggered a drug overutilization review to determine whether the patient's safety may be at risk.

The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

<DATE>

<PRESCRIBER NAME>

<ADDRESS>

<CITY, STATE ZIP>

<RE: CASE MANAGEMENT FILE [###]>

Dear <PRESCRIBER>:

<Plan Name> is sending you this letter to request your assistance in addressing a potential safety matter concerning the health of one of your patients, <Patient Name>. We have determined that <Patient Name> is being prescribed a high dosage of a medication(s) in the opioid class.

<Plan Name> is the Medicare drug plan for your patient, <Patient Name>. We are required by federal law and regulations, as well as by the Centers for Medicare and Medicaid Services (CMS), to identify patterns of inappropriate or medically unnecessary care to ensure the safety of our members.

As part of meeting this requirement, we have implemented a case management approach for our enrollees who are prescribed a high dosage of a medication(s) in the opioid class. We have <listed> <attached> the medication(s) in the opioid class received by <Patient Name>, which includes all prescriber(s) of these medications of which we are aware, the dosage(s) prescribed, and the time period we are reviewing.

[List or attach the information just described].

We are requesting your input regarding whether the current high dosage of medication in the opioid class is appropriate, medically necessary, and safe for <Patient Name>. We will be in touch with you to discuss this case. When multiple prescribers are involved, our goal is to facilitate a consensus among all prescribers as to the appropriate, medically necessary, and safe dosage of opioids for <Patient Name>.

We thank you for your assistance in addressing this matter. Should you have any questions, please contact me at <Contact Information> <and please refer to the case management file number above>.

Sincerely,

<Physician Name>

[Insert beneficiary information]

Sample Part D Drug Overutilization Initial Beneficiary Inquiry Letter CY2013

Instructions: This sample could be used to notify beneficiaries that their plan's records show that they are being prescribed a drug(s) from the opioid class in potentially unsafe high dosages, which has triggered a potential drug overutilization review by the plan to determine whether their safety may be at risk.

The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

<DATE>

<BENEFICIARY NAME>

<ADDRESS>

<CITY, STATE ZIP>

<CASE MANAGEMENT FILE [###]>

Dear <BENEFICIARY NAME>:

<Plan Name> is contacting you because our records show that your doctors have prescribed a high dosage of pain medication for you that can potentially be dangerous to your health. For your safety, Federal law and regulations, as well as by the Centers for Medicare and Medicaid Services (CMS), require us to check to see if you might be receiving inappropriate or medically unnecessary care.

As your case manager, I'll communicate with your doctors who are prescribing the pain medication for you to find out why you're receiving the high dosage, whether it's the best treatment for you, and most importantly, to check that it's safe for you. I'll write you again in the coming weeks to let you know what I've learned.

If you have any questions about this letter, please contact me at <Phone Number> and have ready the case management file number above. Of course, if you have any questions concerning your health care, please contact your doctors.

Sincerely,

<Case Manager>

Sample Part D Drug Overutilization Beneficiary and Prescriber No Change Confirmation Letter CY2013

Instructions: This sample letter should be used if the sponsor confirms that an enrollee's opioid usage is appropriate and medically necessary. The sponsor should cc all relevant prescribers on this letter.

The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

<DATE>

<BENEFICIARY NAME>

<ADDRESS>

<CITY, STATE ZIP>

<RE: CASE MANAGEMENT FILE [#####]>

Dear <BENEFICIARY NAME>:

<Plan Name> contacted you earlier about your pain medication, and we're writing today to tell you the results of our research. After speaking with the doctors who prescribe your medication, we've found that your pain medication is appropriate and medically necessary for you, and therefore covered by <Plan Name> at this time.

Thank you for your patience with this matter. If you have any questions or concerns with this letter, please contact the case manager, <Case Manager Name and Phone Number> and have ready the case management file number above.

Sincerely,

<Case Manager>

Sample Part D Drug Overutilization Notice of Beneficiary Claim Edit Letter CY2013

Instructions: This letter could be used if the sponsor confirms that an enrollee's opioid usage is inappropriate and not medically necessary. The sponsor should cc all relevant prescribers on this letter, as well as the CMS Account Manager. The sponsor would be expected to send a copy of this letter to PartDPolicy@cms.hhs.gov *with the subject line "Notice of Beneficiary Claim Edit."*

The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

<DATE>

<BENEFICIARY NAME>

<ADDRESS>

<CITY, STATE ZIP>

<RE: CASE MANAGEMENT FILE [###]>

Dear <BENEFICIARY NAME>:

<Plan Name> contacted you earlier about your pain medication, and we're writing today to tell you the results of our research. [Plan should insert <After communicating with your doctors who are prescribed this pain medication> OR <Because, after multiple attempts, we weren't able to reach the doctors who prescribed this pain medications> for you, <only the following> <no> pain medication has been found to be appropriate, medically necessary, and most importantly, safe, for your health care.

After fifteen (15) business days have passed from the date of this letter, <only the pain medication below> <no pain medication> will be covered by <Plan Name>.

[When some pain medication will continue to be received by the enrollee, sponsors should describe the claim edit to be implemented by the plan. The following is an example of how a description of such a claim edit could be worded].

<Only <Dosage> of <Drug Name> will be covered every <Number> days for you.

<Plan name> will deny any claim for pain medication that is not described above. This may also happen if you change your Medicare drug plan or doctors. If you decide to change doctors, please contact your case manager, <Case Manager Name and Phone Number>, to make sure you will have coverage for appropriate, medically necessary, and safe, pain medications.

If you believe you need more pain medication than the amount described in this letter, or you disagree with information provided to you by a pharmacist related to refills of your pain medications, you or your prescriber have the right to request a coverage determination by contacting <Plan Name> Customer Service at XXX-XXX-XXXX or going to <Plan Name> website at <Website address>.

If you have any questions or concerns about this letter, please contact the case manager, <Case Manager Name and Phone Number> and have ready the case management file number above. Of course, if you have any questions concerning your health care, please contact your doctors.

Sincerely,

<Physician Name>

[Insert beneficiary information]

Sample Part D Drug Overutilization Sponsor Data Transfer Memorandum CY2013

Instructions: This cover memorandum should be used by a sponsor when an enrollee who is subject to an overutilization protocol disenrolls from the sponsor's plan and enrolls in another in order to alert the successor sponsor about the enrollee's opioid overutilization and to provide the successor sponsor with the records and actions generated by the sponsor's overutilization review of the enrollee.
The sponsor may replace <Plan name> with either "the Plan" or "our Plan" throughout the notice.

DATE: <Date>

TO: Successor Sponsor

FROM: Current Sponsor

RE: Enrollee Subject to an Overutilization Protocol

This memo and the file accompanying is to alert <Successor Sponsor> that <Current Sponsor> has received notice within the last two weeks that <Beneficiary Name> has disenrolled from <Plan Name> and enrolled in <Plan Name> effective <Date>. This enrollee has been subject to an opioid overutilization protocol since <date> at <Plan Name>. This overutilization protocol consists of [*The following is an example of how a description of such a claim edit could be worded*].

<Only <Dosage> of <Drug Name> was covered every <Number> days>.

Accompanying this memorandum are copies of the records from the retrospective DUR review/case management that was conducted by <Current Sponsor> upon which the decision to implement the overutilization protocol was based. Specifically, the following minimum necessary records are included:

[List the records that are included. Examples of records that could be included are:

a) clinical threshold and/or prescription pattern that triggered case management;
b) copies of medical records;
c) beneficiary drug utilization history;
d) correspondence with prescribers and the beneficiary;
e) notes documenting telephone conversations;
f) documentation of the decision arrived at through case management; and
g) description of the beneficiary-specific POS edit that was implemented.

If you have any questions concerning this memorandum, please contact <Case Manager> at <Contact Information.>

[*Insert beneficiary information]*